New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplements Approved (CY 2009)

NDA Efficacy Supplements Approved (N, SE1-SE7)

ESTABLISHED NAME	APPLICANT	APPLICATION NUMBER	SUPPLEMENT TYPE	SUPPLEMENT NUMBER	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (IN MONTHS)	INDICATIONS
LIDOCAINE HYDROCCLORIDE MONOHYDRATE	ANESIVA	022114	SE5	001		10-Mar-08	08-Jan-09	10.0	PROVIDES FOR THE USE ON INTACT SKIN TO PROVIDE TOPICAL LOCAL ANALGESIA PRIOR TO VENIPUNCTURE IN ADULTS.
RALTEGRAVIR POTASSIUM	MERCK AND CO	022145	SE7	001		31-Mar-08	29-Jan-09	10.0	PROVIDES FOR THE UPDATE OF THE PACKAGE INSERT AND PATIENT PACKAGE INSERT WITH THE 48 WEEK DATA FROM STUDIES TO SUPPORT USE OF THIS DRUG FOR THE TRATMENT OF HIV-1 INFECTION, IN COMBINATION WITH OTHER ANTIRETOVIRAL AGENTS, IN TREATMENT-EXPERIENCED ADULT PATIENTS.
LAMIVUDINE/ZIDOVUDINE	GLAXOSMITHKLINE	020857	SE5	023	Y	13-Jun-08	02-Feb-09	7.7	PROVIDES FOR THE TREATMENT OF HIV-1 INFECTION, IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS, IN PEDIATRIC PATIENTS GREATER THAN OR EQUAL TO 30 KILOGRAMS.
GLATIRAMER ACETATE	TEVA NEUROSCIENCE	020622	SE1	057		01-May-08	27-Feb-09	9.9	PROVIDES FOR THE USE FOR REDUCTION OF THE FREQUENCY OF RELAPSES IN PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS (RRMS), INCLUDING PATIENTS WHO HAVE EXPERIENCED A FIRST CLINICAL EPISODE AND HAVE MRI FEATURES CONSISTENT WITH MULTIPLE SCLEROSIS.
BUDESONIDE/ FORMOTEROL	ASTRAZENECA	021929	SE1	012		29-Apr-08	27-Feb-09	10.0	PROVIDES FOR THE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD).
SOMATROPIN, BIOSYNTHETIC	LILLY	019640	SE1	068		18-Jan-08	12-Mar-09	13.8	PROVIDES FOR THE TREATMENT OF SHORT STATURE IN PEDIATRIC PATIENTS SMALL FOR GESTATIONAL AGE WHO DO NOT MANIFEST CATCH UP GROWTH BY AGE 2 TO 4 YEARS
ZOLEDRONIC ACID INJECTION 5MG	NOVARTIS PHARMS	021817	SE1	003		15-Feb-08	13-Mar-09	12.9	PROVIDES FOR THE INDICATION OF THE TREATMENT AND PREVENTION OF GLUCOCORTICOID-INDUCED OSTEOPOROSIS IN PATIENTS EXPECTED TO BE ON GLUCOCORTICOIDS FOR AT LEAST 12 MONTHS.
OLANZAPINE; FLUOXETINE HYDROCHLORIDE	LILLY	021520	SE1	012	Y	19-Sep-08	19-Mar-09	6.0	PROVIDES FOR THE ADDITION OF A NEW INDICATION, ACUTE TREATMENT OF TREATMENT RESISTANT DEPRESSION (TRD), AND THE ADDITION OF A MEDICATION GUIDE
ESCITALOPRAM OXALATE 5/10/20MG TABLETS	FOREST LABS	021323	SE5	030		23-May-08	19-Mar-09	9.9	PROVIDES FOR THE ACUTE AND MAINTENANCE TREATMENT OF ADOLESCENT MAJOR DEPRESSIVE DISORDER (MDD).
ESCITALOPRAM OXALATE 5/10/20MG TABLETS	FOREST LABS	021323	SE5	031		13-Jun-08	19-Mar-09	9.2	PROVIDES FOR THE ACUTE AND MAINTENANCE TREATMENT OF ADOLESCENT MAJOR DEPRESSIVE DISORDER (MDD).
ESCITALOPRAM OXALATE	FOREST LABS	021365	SE5	021		23-May-08	19-Mar-09	9.9	PROVIDES FOR THE ACUTE AND MAINTENANCE TREATMENT OF ADOLESCENT MAJOR DEPRESSIVE DISORDER (MDD).
ESCITALOPRAM OXALATE	FOREST LABS	021365	SE5	022		13-Jun-08	19-Mar-09	9.2	PROVIDES FOR THE ACUTE AND MAINTENANCE TREATMENT OF ADOLESCENT MAJOR DEPRESSIVE DISORDER (MDD).
TIGECYCLINE	WYETH PHARMS INC	021821	SE1	013		22-Sep-08	20-Mar-09	5.9	PROVIDES INFORMATION FOR THE INDICATION OF COMMUNITY ACQUIRED BACTERIAL PNEUMONIA.

TIGECYCLINE	WYETH PHARMS INC	021821	SE1	018		22-Sep-08	20-Mar-09	5.9	PROVIDES INFORMATION FOR THE ADDITION OF PATHOGENS TO THE COMPLICATED INTRA-ABDOMINAL INDICATION.
TIGECYCLINE	WYETH PHARMS INC	021821	SE1	017		22-Sep-08	20-Mar-09	5.9	PROVIDES INFORMATION FOR THE ADDITION OF PATHOGENS TO THE COMPLICATED SKIN AND SKIN STRUCTURE INDICATION
HYDROMORPHONE HYDROCHLORIDE	PURDUE PHARM PRODS	019034	SE2	018		04-Sep-07	30-Apr-09	19.9	PROVIDES FOR ADDITIONAL STRENGTHS OF DILAUDID INJECTION FOR THE MANAGEMENT OF PAIN IN PATIENTS WHERE AN OPIOID ANALGESIC IS APPROPRIATE.
ANASTROZOLE	ASTRAZENECA (UK)	020541	SE7	024		01-Jul-08	30-Apr-09	10.0	PROVIDES FOR THE FINAL STUDY REPORTS (12 MONTH AND 24 MONTH DATA) OF A DOUBLE BLIND, RANDOMIZED COMPARISON OF THE DRUG IN EARLY BREAST CANCER PATIENTS. RESULTS OF THE HYPERLIPIDEMIA SUBSTUDY WAS CONTAINED IN THE 12 MONTH STUDY.
ALMOTRIPTAN MALATE	ORTHO MCNEIL JANSSEN	021001	SE5	011	Y	31-Oct-08	30-Apr-09	6.0	PROVIDES FOR THE ACUTE TREATMENT OF PEDIATRIC MIGRAINE.
SILDENAFIL CITRATE	PFIZER	021845	SE1	006		07-Nov-08	07-May-09	6.0	PROVIDES FOR THE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION TO IMPROVE EXERCISE ABILITY AND DELAY CLINICAL WORSENING.
AMLODIPINE BESYLATE/OLMESARTAN MEDOXOMIL	DAIICHI SANKYO	022100	SE1	002		11-Jul-08	11-May-09	10.0	PROVIDES FOR THE USE AS INITIAL THERAPY IN PATIENTS LIKELY TO NEED MULTIPLE ANTIHYPERTENSIVE AGENTS TO ACHIEVE THEIR BLOOD PRESSURE GOALS.
RISPERIDONE	ORTHO MCNEIL JANSSEN	021346	SE1	025		26-Mar-09	15-May-09	1.6	PROVIDES FOR THE USE AS ADJUNCTIVE THERAPY WITH LITHIUM OR VALPROATE FOR THE MAINTENANCE TREATMENT OF BIPOLAR I DISORDER.
RISPERIDONE	ORTHO MCNEIL JANSSEN	021346	SE1	028		21-Jul-08	15-May-09	9.8	PROVIDES FOR THE MAINTENANCE OF BIPOLAR I DISORDER.
DASATINIB 20/50/70MG TABLETS	BRISTOL MYERS SQUIBB	021986	SE2	004		04-Aug-08	21-May-09	9.5	PROVIDES FOR THE TREATMENT OF ADULTS WITH CHRONIC , ACCELERATED, OR MYELOID OR LYMPHOID BLAST PHASE CHRONIC MYELOID LEUKEMIA WITH RESISTANCE OR INTOLERANCE TO PRIOR THERAPY INCLUDING IMATINIB AND THE TREATMENT OF ADULTS WITH PHILADELPHIA CHROMOSOME-POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA WITH RESISTANCE OR INTOLERANCE TO PRIOR THERAPY.
TADALAFIL	ELI LILLY CO	022332	N	000		24-Jul-08	22-May-09	9.9	PROVIDES FOR THE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION TO IMPROVE EXERCISE ABILITY.
IMATINIB MESYLATE TABLETS	NOVARTIS PHARMS	021588	SE7	026		01-Aug-08	27-May-09	9.8	PROVIDES FOR THE TREATMENT OF NEWLY DIAGNOSED ADULT PATIENTS WITH PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA IN THE CHRONIC PHASE.
ZOLEDRONIC ACID INJECTION 5MG	NOVARTIS PHARMS	021817	SE1	004		30-Jul-08	29-May-09	10.0	PROVIDES FOR THE PREVENTION OF OSTEOPOROSIS IN POST MENOPAUSAL WOMEN.
RIFAPENTINE	SANOFI AVENTIS US	021024	SE7	008		23-Apr-09	01-Jun-09	1.3	PROVIDES DRAFT LABELING FOR THE PACKAGE INSERT.
PARICALCITO CAPSULES	ABBOTT LABS	021606	SE1	004		07-May-08	29-Jun-09	13.7	PROVIDES FOR THE PREVENTION AND TREATMENT OF SECONDARY HYPERPARATHYROIDISM ASSOCIATED WITH CHRONIC KIDNEY DISEASE (CKD) STAGE 5 IN PATIENTS ON HEMODIALYSIS OR PERITONEAL DIALYSIS.

NDA Efficacy Supplements Approved (SE8)

ESTABLISHED NAME	APPLICANT	APPLICATION TYPE	APPLICATION NUMBER	SUPPLEMENT TYPE	SUPPLEMENT NUMBER	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (IN MONTHS)
TELBIVUDINE	NOVARTIS	N	022011	SE8	001		24-Dec-07	23-Jan-09	13.0
FLUOXETINE HYDROCHLORIDE	LILLY RES LABS	N	018936	SE8	077	Y	19-Sep-08	19-Mar-09	6.0
OLANZAPINE	LILLY	N	020592	SE8	039	Y	19-Sep-08	19-Mar-09	6.0
OLANZAPINE	LILLY	N	021086	SE8	021	Y	01-Dec-08	19-Mar-09	3.6
SALMETEROL/FLUTICASONE PROPIONATE INHALA	GLAXOSMITHKLINE	N	021077	SE8	036		19-Sep-08	31-Mar-09	6.3
LOPINAVIR; RITONAVIR	ABBOTT LABS	N	021251	SE8	026		25-Jun-08	20-Apr-09	9.8
LOPINAVIR; RITONAVIR	ABBOTT LABS	N	021906	SE8	017		25-Jun-08	20-Apr-09	9.8
NICOTINE POLACRILEX	GLAXOSMITHKLINE	N	018612	SE8	052		08-Jul-08	06-May-09	9.9
NICOTINE POLACRILEX	GLAXOSMITHKLINE	N	020066	SE8	033		08-Jul-08	06-May-09	9.9
TACROLIMUS	ASTELLAS	N	050708	SE8	027		15-May-09	19-May-09	0.1
TACROLIMUS	ASTELLAS	N	050709	SE8	021	Y	15-May-09	19-May-09	0.1
LISDEXAMFETAMINE DIMESYLATE	NEW RIVER PHARMACEUT	N	021977	SE8	007		31-Jul-08	22-May-09	9.7
OLOPATADINE HCL 0.6%	ALCON	N	021861	SE8	001		19-Aug-08	17-Jun-09	9.9
ESOMEPRAZOLE MAGNESIUM 20/40MG	ASTRAZENECA	N	021957	SE8	005		18-Dec-08	18-Jun-09	6.0
CASPOFUNGIN ACETATE	MERCK	N	021227	SE8	023		05-Sep-08	26-Jun-09	9.7

BLA Efficacy Supplements Approved

PROPER NAME	APPLICANT	BLA NUMBER	SUPPLEMENT NUMBER	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (IN MONTHS)	INDICATION
OPRELVEKIN	WYETH PHARMACEUTICAL	L 103694	1008.0	S10	27-Aug-99	13-Feb-09	113.7	REVISE THE CLINICAL PHARMACOLOGY: PHARMACOKINETICS SUBSECTION OF THE PACKAGE INSERT AND TO INCLUDE A GERIATRIC USE SUBSECTION

PEGINTERFERON ALFA-2B	SCHERING CORPORATION	L 103949	5125.0	S10	1-Aug-06	10-Mar-09	31.3	TO EXPAND THE INDICATION TO INCLUDE THE RETREATMENT OF CHRONIC HEPATITIS C SUBJECTS WHO HAVE FAIL OR RELAPSE AFTER PREVIOUS TREATMENT WITH COMBINATION ALPHA INTERFERON/RIBAVIRIN THERAPY
ABOBOTULINUMTOXINA	IPSEN BIOPHARM LIMITED	L 125274	1.0	S10	14-Mar-08	29-Apr-09	13.5	FORMERLY BLA 125286/0 -- (CONVERTED TO EFFICACY SUPPLEMENT UNDER THIS BLA) FOR TEMPORARY IMPROVEMENT IN THE APPEARANCE OF MODERATE TO SEVERE GLABELLAR LINES
BEVACIZUMAB	GENENTECH, INC.	L 125085	169.0	P06	3-Nov-08	5-May-09	6.0	INCLUDE A NEW INDICATION FOR BEVACIZUMAB FOR THE TREATMENT OF PATIENTS WITH GLIOBLASTOMA WITH PROGRESSIVE DISEASE FOLLOWING PRIOR THERAPY.
PEGINTERFERON ALFA-2B	SCHERING CORPORATION	L 103949	5172.0	S10	8-Jul-08	8-May-09	10.0	TO UPDATE THE PI WITH THE RESULTS OF THE IDEAL STUDY, P03471; EXPANDING THE INDICATION TO INCLUDE PATIENTS WITH HISTOLOGIC EVIDENCE OF CIRRHOSIS AND NORMAL AND ABNORMAL ALT LEVESL, A TWO-STEP DOSE REDUCTION SCHEME AND WEIGHT-BASED DOSING OF REBETOL FOR PA
LARONIDASE	BIOMARIN PHARMACEUTICAL INC.	L 125058	160.0	S10	10-Dec-07	20-May-09	17.3	CHANGES TO ADVERSE REACTIONS, USE IN SPECIFIC POPULATIONS, CLINICAL PHARMACOLOGY, AND CLINICAL STUDIES SECTION OF THE PACKAGE INSERT.
LARONIDASE	BIOMARIN PHARMACEUTICAL INC.	L 125058	161.0	S10	17-Dec-07	20-May-09	17.1	UPDATE TO ADVERSE REACTIONS, CLINICAL PHARMACOLOGY, AND CLINICAL STUDIES SECTIONS OF THE PACKAGE INSERT WITH CLINICAL DATA.

Supplement Type	Description
N	TYPE 6 NDA - NEW INDICATION
SE1	NEW OR MODIFIED INDICATION
SE2	NEW DOSAGE REGIMEN
SE3	NEW ROUTE OF ADMINISTRATION

SE4	COMPARATIVE EFFICACY CLAIM
SE5	PATIENT POPULATION ALTERED
SE6	CHANGE THE MARKETING STATUS FROM PRESCRIPTION TO OVER-THE-COUNTER USE
SE7	COMPLETE THE TRADITIONAL APPROVAL OF A PRODUCT ORIGINALLY APPROVED UNDER SUBPART H (ACCELERATED APPROVAL)
SE8	INCORPORATE OTHER INFORMATION BASED ON AT LEAST ONE ADEQUATE AND WELL-CONTROLLED CLINICAL STUDY

Updated through 6/30/09